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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,677	04/15/2005	Margaret Forney Prescott	PA/4-32723A	1716

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
KUDLA, JOSEPH S	

ART UNIT	PAPER NUMBER
4133	

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11/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,677	PRESCOTT, MARGARET FORNEY	
	Examiner	Art Unit	
	Joseph S. Kudla	4133	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 5-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1 and 5-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 9 and 16-18, drawn to a method for the treatment of atherosclerosis comprising administering a bisphosphonate.

Group II, claim(s) 5, drawn to a method for the prevention and treatment of atherosclerotic calcification of blood vessels and valves in a patient comprising administering a bisphosphonate.

Group III, claim(s) 6, drawn to a method for the stabilization of atherosclerotic plaques comprising administering a bisphosphonate.

Group IV, claim(s) 7, drawn to a method for preventing or treating smooth muscle cell proliferation and migration in hollow tubes, or increased cell proliferation or decreased apoptosis or increased matrix deposition comprising administration of a bisphosphonate.

Group V, claim(s) 8, 11 and 15, drawn to a method for the treatment of intimal thickening in vessel walls comprising administration of a bisphosphonate.

Group VI, claim(s) 10, drawn to a method for the treatment of intimal thickening in vessel walls or stabilization of vulnerable atherosclerotic plaques comprising the controlled delivery from a catheter-based device, intraluminal medical device or device applied to the external/adventitial aspect of the vessel with an amount of a bisphosphonate

Group VII, claim(s) 12-14, drawn to a drug delivery device or system comprising a) a medical device adapted for local application or administration in hollow tubes and b) a therapeutic dosage of zoledronic acid or a pharmaceutically acceptable salt thereof being releasably affixed to the medical device.

2. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: There is no special technical feature in the instant claim set.

The technical feature that applicant states in claim 1 is a method for the treatment of atherosclerosis comprising administering a bisphosphonate. The technical feature that applicant states in claim 1 is known in the art. US Patent 5,157,027 in column 1, lines 44-47 teach the use of a bisphosphonate for the treatment of

atherosclerosis. The technical feature that applicant states in claim 6 is a method for preventing or treating smooth muscle cell proliferation comprising administering a bisphosphonate. The technical feature that applicant states in claim 6 is known in the art. US Patent Application 2003/0064965 discloses in the last sentence of paragraph 28 the use of a bisphosphonate to treat smooth muscle cell proliferation. Claims 1 and 6 do not have a special technical feature and thus the claims lack unity. Applicant is required to elect a group to be examined on the merits.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

The bisphosphonate compounds in claims 16-18.
The second compound listed in claims11-13.
The type of delivery route listed in claim 15.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

4. The claims are deemed to correspond to the species listed above in the following manner:

The following claim(s) are generic: claims 11 and 13-18.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: There is no special technical feature in each of the species.

Bisphosphonate Compound

Claims 16-18 are generic due to a plurality of the following disclosed patentably distinct antibiotic species represented in claims 16-18. The compounds of claims 16-18 encompass many different and distinct compositions. The compositions vary distinctly in their structures and functions. Thus, an individual search is required of each

individual composition. Therefore, Applicant is required to elect a specific compound, to which the elected invention will be examined on the merits as drawn to (in the event that the elected compound cannot be found, the elected structure will be opened to a reasonable core); as well as identifying those claims to which the elected compound/invention is drawn.

Type of Second Compound

If Applicant chooses to elect either Invention V or VII, Claims 11, 12 and 13 are generic due to a plurality of the following disclosed patentably distinct antibiotic species represented in claims 11, 12 and 13. The compounds of claims 11, 12 and 13 encompass many different and distinct compositions. The compositions vary distinctly in their structures and functions. Thus, an individual search is required of each individual composition. Therefore, Applicant is required to elect a specific compound, to which the elected invention will be examined on the merits as drawn to; as well as identifying those claims to which the elected compound/invention is drawn.

Type of Delivery Route

If Applicant chooses to elect Invention V, Claim 15 is generic due to a plurality of the following disclosed patentably distinct delivery route species represented in claim 15. The delivery routes encompass many different and distinct methods. The methods vary distinctly in their structures of the components and functions. Thus, an individual search is required of each individual method of delivery. Therefore, Applicant is

required to elect a specific delivery method, to which the elected invention will be examined on the merits as drawn to; as well as identifying those claims to which the elected compound/invention is drawn..

6. Effective November 1, 2007, if applicant wishes to present more than 5 independent claims or more than 25 total claims in an application, applicant will be required to file an examination support document (ESD) in compliance with 37 CFR 1.265 before the first Office action on the merits (hereafter "5/25 claim threshold"). See Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46715 (Aug. 21, 2007), 1322 Off. Gaz. Pat. Office 76 (Sept. 11, 2007) (final rule). The changes to 37 CFR 1.75(b) apply to any pending applications in which a first Office action on the merits (FAOM) has not been mailed before November 1, 2007. Withdrawn claims will not be taken into account in determining whether an application exceeds the 5/25 claim threshold. For more information on the final rule, please see http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html.

In response to the restriction requirement set forth in this Office action, applicant is required to file an election responsive to the restriction requirement. Applicant may not file a suggested restriction requirement (SRR) in lieu of an election responsive to the restriction requirement as a reply. A SRR alone will not be considered a *bona-fide* reply to this Office action.

If applicant elects an invention that is drawn to no more than 5 independent claims and no more than 25 total claims, applicant will not be required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims. If the elected invention is drawn to more than 5 independent claims or more than 25 total claims, applicant may file an amendment canceling a number of elected claims so that the elected invention would be drawn to no more than 5 independent claims and no more than 25 total claims.

If the restriction requirement is mailed on or after November 1, 2007, applicant is also required to file an ESD in compliance with 37 CFR 1.265 that covers each of the elected claims, unless the elected invention is drawn to no more than 5 independent claims and no more than 25 total claims taking into account any amendment to the claims. To avoid the abandonment of the application, the ESD (if required) and the election must be filed within **TWO MONTHS** from the mailing date of this Office action. The two-month time period for reply is extendable under 37 CFR 1.136.

If the restriction requirement is mailed before November 1, 2007, the election must be filed within **ONE MONTH** or THIRTY DAYS, whichever is longer, from the mailing date of this Office action. The time period for reply is extendable under 37 CFR 1.136. Furthermore, if the elected invention is drawn to more than 5 independent claims or more than 25 total claims taking into account any amendment to the claims, the

Office will notify applicant and provide a time period in which applicant is required to file an ESD in compliance with 37 CFR 1.265 covering each of the elected claims or amend the application to contain no more than 5 independent elected claims and no more than 25 total elected claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Kudla whose telephone number is (571) 270-3288. The examiner can normally be reached on 9am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JK

MICHAEL MELLER
PRIMARY EXAMINER